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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,448	03/05/2001	Santu Bandyopadhyay	A34065	2808

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,448	BANDYOPADHYAY ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/31/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21,23-26 and 28-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21,23-26 and 28-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

1. Applicant's amendments and remarks filed 1/31/05 are acknowledged. In view of Applicant's amendments all previous objections to the specification have been withdrawn. Additionally, in view of Applicant's amendment, the previous rejections under the first paragraph of 35 U.S.C. 112 of Claims 14-22 and 27-28 for the introduction of new matter into the claims, as well as the previous rejection under the second paragraph of 35 U.S.C. 112, have been withdrawn.

2. In view of Applicant's amendments filed 1/31/05, all claims now read on a method of producing mature dendritic Langerhans cells (DLCs). Accordingly, Claims 14-21, 23-26, 28-34, and newly added Claims 35-38, are being acted upon.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 32-33 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

> the method of Claims 32-33 wherein more than about 50% of the mature dendritic cells have dendritic processes and display reactivity to anti-HLA-DR, anti-CD40, and anti-CD86 monoclonal antibodies and less than about 20% of the mature dendritic cells display reactivity to anti-CD1a, anti-CD80, and anti-CD83 monoclonal antibodies.

Applicant argues that the amending of Claim 32 to recite a method of producing mature human DLCs overcomes the rejection.

Applicant relies on the specific example of pages 7-8 to support generic claims. Said support is improper. While Claim 32 has been limited to a method of producing mature *human* DLCs,

the example which Applicant asserts supports the claims discloses many more limitations than are claimed. For example, the method of the example comprises the use of a specific medium, RPMI-1640 and 2% FCS; no such limitations are recited in the claims. Additionally, it is unclear where the support for the limitation of, "wherein more than about 50% of the mature dendritic cells have dendritic processes and display reactivity to anti-HLA-DR, anti-CD40, and anti-CD86 monoclonal antibodies" is to be found. Also note that the example discloses *approximately* 20% of the cells express CD1a, CD1b, CD80, or CD83, but Claim 32 recites "*less than about* 20% of the mature dendritic cells display reactivity to anti-CD1a, anti-CD80, and anti-CD83 monoclonal antibodies".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14-17, 21, 23, 26, 28-34, and newly added Claims 35-37, stand/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Semple et al. (1991).

As set forth previously, Semple et al. teaches an in vitro method for producing mature dendritic Langerhans cells, comprising culturing cells selected from the group consisting of peripheral blood monocytes and bone marrow cells in a medium (RPMI-1640) containing mammalian (human) platelets; and incubating the culture at about 30°C to about 40°C for a period (about 2 to about 8 days) sufficient to enable formation of mature dendritic Langerhans cells, wherein the medium omits an exogenous cytokine including GM-CSF or IL-4 (see particularly page 2620, *PBMC/platelet APC cultures*). Note that the intention of the method as set forth in Claim 21 adds no patentable weight to the method. The method of the reference performs the same steps as the method of the instant claims and would, thus, comprise the same results. Likewise, the results of Claim 32 would also be inherent to the method of the reference.

Applicant's arguments have been fully considered but they have not been found persuasive. Applicant notes the differences in the objects of the invention of the instant claims and the reference, Applicant argues that the reference fails to disclose the use of pure, isolated platelets and requires the use of acid-washed platelets that "removes surface platelet antigens that may be necessary to facilitate the development of mature dendritic Langerhans cells from PBMC in the present invention. Applicant asserts that, in the absence of some platelet surface

antigens, the steps taught by Semple do not disclose each and every element of the claimed invention".

Applicant is advised that if a reference teaches the steps of a claimed method, regardless of intentions, the reference anticipates the claimed invention. Regarding the use of "pure, isolated platelets", the specification discloses only the use of platelets isolated by high speed centrifugation, regardless, the limitation is not part of the claimed invention. Likewise, the exclusion of the use of acid-washed platelets also comprises an unclaimed limitation. Note that the specification discloses nothing regarding the mechanism by which the method of the instant claims functions. Accordingly, Applicant's assertion that "surface platelet antigens that may [note the *may*] be necessary to facilitate the development of mature dendritic Langerhans cells from PBMC" are lost in acid-washing, comprises nothing more than an attorney's speculation.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Semple et al. (1991).

As set forth previously, Semple et al. has been described above. The reference teaching differs from the claimed invention only in that it does not teach the use of fetal calf serum in the method. The method of the reference employs human AB serum; it is well known, however, that fetal calf serum is a much cheaper substitute for human serum in cell culture methods wherein human serum is not required (i.e., methods wherein the product is not intended for administration to humans, such as the claimed method). Regarding concentrations of serum used in culture, the choice of serum concentrations comprises only routine optimization of the claimed method, said routine optimization falling well within the purview of one of skill in the art at the time of the invention.

Applicant's arguments have been fully considered but they have not been found persuasive. Applicant argues that as Semple et al is deficient, the rejection should be withdrawn.

See section 6 above.

9. The following are new grounds of rejection necessitated by Applicant's amendment.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 14-21, 23-26, 28-34, and newly added Claims 35-37, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) The term "phylogenetically close species" is vague and indefinite as the term is not defined in the specification. It is unclear which species would be considered "phylogenetically close", and which would not. For example, it is clear that the Inventors consider mice and rats to be "phylogenetically close", but it is unclear whether species such as mice and guinea pigs, or mice and rabbits, or mice and beavers, would also be considered close. Accordingly, the metes and bounds of the claims cannot be established.

B) Claims 24 and 34 are vague and indefinite in that the product of the claims, human dendritic Langerhans's cells, is not the intended product set forth in the preamble of the independent claims, i.e., *mature* human dendritic Langerhans's cells.

12. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Semple et al. (1991) in view of U.S. Patent No. 6,828,157.

Semple et al. has been described above.

The reference teaching differs from the claimed invention only in that it does not teach the analyzing of the morphology of the cells produced nor the use of flow cytometry in said analysis.

The '157 patent teaches the analysis of cells, including cell morphology, by flow cytometry. The reference refers to flow cytometry as the "gold standard" for analysis, such as immunophenotyping, of hematopoietic cells (see particularly, Background of the Invention).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Semple et al. and analyze the products (including cell morphology) by flow cytometry, as taught by the '157 patent. One of ordinary skill in the art at the time the invention was made would have been perform said analysis as a routine determination of the outcome of the method, employing flow cytometry, i.e., the "gold standard" for analysis, such as immunophenotyping, of hematopoietic cells.

13. No claim is allowed.

14. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

17. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

4/11/08

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